

REMARKS

Claims 1-4, 6, 11, and 12 constitute the pending claims in the present application.

Applicants cancel, without prejudice, claim 12. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note that the amendments put forth in Paper 17 have been entered in full.
2. The drawings are objected to for the reasons set forth in the Notice of Draftperson's Patent Drawing Review (PTO-948). Applicants enclose herewith corrected drawings which are believed to obviate the objection.
3. The specification is objected to for allegedly failing to comply with the requirements of 37 CFR 1.821 through 1.825 regarding reference to nucleotide and amino acid sequences. Applicants' amendments to the specification are believed to obviate the objection.
4. Claims 1, 2, 4, 6, and 11 are rejected under 35 U.S.C. 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

Applicants contend that the term "hedgehog therapeutic" is amply described in the specification such that one of skill in the art can readily appreciate the metes and bounds of the claimed subject matter. Nevertheless, Applicants have amended the claims such that the claimed subject matter is described using means-plus-function language, and the term "hedgehog therapeutic" is no longer recited in the present claims. Applicants' amendments do not indicate acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

Additionally, the Examiner objected to the recitation of "comprising NGF" in claim 11 versus "consisting essentially of NGF" in claim 12 as allegedly indefinite. Applicants fail to see the confusion created by referring to the components of the composition using terms commonly used and readily understood in the art (e.g., comprising and consisting essentially of).

Nevertheless, Applicants' amendments to the claims such that the claimed subject matter is

described using means-plus-function language renders this rejection moot. Applicants note, however, that Applicants' amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are requested.

5. Claims 1-4, 6, 11, and 12 are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to enable one of skill in the art to practice the claimed invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

Applicants contend that the previously pending claims were enabled throughout their scope. Nevertheless, Applicants have amended the claims in compliance with 35 U.S.C. § 112, sixth paragraph, and Applicants' amendments to the claims render the previous rejection moot. Applicants respectfully request that the Examiner reconsider this rejection in light of the currently pending means-plus-function claims presented above and Applicants' arguments presented herein. Should the Examiner wish to maintain the rejection, Applicants respectfully request that the Examiner clarify the basis for applying this grounds of rejection to a means-plus-function claim so that Applicants may adequately respond to the particular rejection.

It is difficult to imagine the circumstances under which a means-plus-function claim could be rejected as lacking sufficient written description or enablement. As is clear from the very language of the statute, claims interpreted under 35 U.S.C. § 112, sixth paragraph, are construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. Thus, the claims are so intimately tied to the disclosure of the specification – for the specification lays the foundation for the scope of the claim in an intimate and inextricable manner – that the claims by definition must be adequately described. If the Examiner bases this rejection on the equivalents that fall within the scope of the claim, Applicants direct the Examiner's attention to MPEP 2182: "The specification need not describe the equivalents of the structures, material, or acts corresponding to the means- (or step-) plus-function claims. See *In re Noll*, 545 F.2d 141, 149-50, 191 USPQ 721, 727 (CCPA 1976) ('The meaning of "equivalents" is well understood in patent law, ... and an applicant need not describe in the specification the full range of equivalents of his invention.' (citation omitted).'" Applicants

will address any additional issues surrounding the scope and interpretation of the recently added claims below.

As has been stated above, claims governed by 35 U.S.C. § 112, sixth paragraph, are construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. The present claims use two different means-plus-function phrases: means for binding *patched*, and thereby activating hedgehog signaling, and neurotrophic factor means. For both phrases, one of skill in the art would recognize that the corresponding materials in the specification are (a) the naturally occurring hedgehog proteins and fragments thereof that bind to *patched*, and promote hedgehog signaling, and (b) the neurotrophic factors, and bioactive fragments thereof, that promote the survival of neuronal cells. The equivalents within the literal scope of the claim, as has been pointed out above, are determined as a matter of law. Applicants invite the Examiner to make of record why Applicants are not enabled for use of a composition that is insubstantially different from a hedgehog protein, that is interchangeable with a hedgehog protein, or that performs substantially the same function, in substantially the same way, to achieve substantially the same result as the hedgehog protein itself.

In evaluating the enablement of the claimed subject matter, both the courts and the MPEP have acknowledged that some experimentation is permissible, as long as that experimentation is not undue (MPEP 2164.04). “An extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance.” *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). However, the courts have been clear that the determination of whether undue experimentation is required should not be made based solely on the time and cost involved in conducting such experimentation. “The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). “Time and expense are merely factors in this consideration and are not the controlling factors.” *United States v. Telecommunications Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989).

Applicants contend that the pending claims are enabled throughout their scope, and that Applicants' amendments to the claims obviate the rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

6. Claims 1-4, 6, 11, and 12 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 5884079 (Ingham et al.) in view of Molses et al. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

Applicants have amended the claims to more particularly point out certain embodiment of Applicants' invention. Specifically, that the components of the claimed composition (e.g., the means for binding patched and thereby activating hedgehog signaling and the neurotrophic factor means) act synergistically to promote the differentiation and survival of the cholinergic neurons. Support for Applicants' amendments can be found in Applicants' examples (page 74, line 5-page 75, line 2). Such synergistic effects are neither taught nor suggested by the prior art references, and accordingly, the prior art fails to render the claimed invention obvious.

To establish a *prima facie* case of obviousness, "all the claim limitations must be taught or suggested by the prior art." MPEP 2143.03; *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Furthermore, when combining prior art references to arrive at a claimed invention, the criteria for obviousness requires that there be a reasonable expectation of success. MPEP 2143.02; *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants contend that the combination of Ingham et al. and Molses et al. fail to satisfy these criteria, and thus fail to render the claimed invention obvious. Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,



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